

## REMARKS

This complete Response includes a request for a one month extension of time and the appropriate fee under 37 CFR § 1.17

Claims 1, 3, 5-8, 10-13, and 15-19 are pending in this application. By this amendment, Claim 4 is cancelled, and Claims 1 and 19 are amended. No new matter has been added. Reconsideration of the application in view of the above amendments and the following remarks is respectfully requested.

**I. THE CLAIMS ARE PATENTABLE OVER U.S. PATENT No. 6,746,472 TO FRAZIER ET AL.**

Claims 1, 3-5, 8, 13, 15, and 19 were rejected under 35 USC 102 (e) as being anticipated by U.S. Patent No. 6,746,472 to Frazier et al. (hereinafter "Frazier"). This rejection is respectfully traversed.

As amended, Claim 1 recites a delivery apparatus for performing a surgical procedure comprising: a flexible catheter capable of assuming an angular configuration at a predetermined time during the surgical procedure, wherein the flexible catheter has an outer catheter and an inner catheter movably disposed in the outer catheter, the inner catheter adapted to bend within the outer catheter; a penetration apparatus disposed within the inner catheter, the penetration apparatus further comprises a first end having a tip for creating an aperture, and a second end that is substantially free; at least one fastener in communication with the penetration apparatus; and a sealant material associated with at least a portion of the fastener.

Claims 8 and 13 of the present application are directed to a delivery apparatus for performing a surgical procedure. The delivery apparatus, as recited in Claims 8 and 13, comprises; a flexible catheter capable of assuming an angular configuration at a

predetermined time during the surgical procedure, wherein the flexible catheter has an outer catheter and an inner catheter movably disposed in the outer catheter; a penetration apparatus disposed within the inner catheter, the penetration apparatus further comprises a first end having a tip for creating an aperture, and a second end that is substantially free; at least one fastener in communication with the penetration apparatus; and a sealant material associated with at least a portion of the fastener.

Claim 18 recites a method for securing a prosthetic graft to a vessel at a surgical site, comprising the steps of: advancing a delivery apparatus to the surgical site; activating the delivery apparatus to contact the surgical site; advancing the delivery apparatus wherein the delivery apparatus creates an aperture at the surgical site; and releasing a fastener to the surgical site to secure the prosthetic graft to the vessel, wherein at least one portion of the fastener further comprises a sealant material.

Claim 19 of the present application is directed to a delivery apparatus for performing a surgical procedure. The delivery apparatus, as recited in the Claim 19, comprises; a flexible catheter capable of assuming an angular configuration at a predetermined time during the surgical procedure; a penetration apparatus having a solid core disposed within the inner catheter, the penetration apparatus further comprises a first end having a tip for creating an aperture, and a second end that is substantially free; at least one fastener in communication with the penetration apparatus; and a sealant material associated with at least a portion of the fastener.

Frazier discloses an anastomosis catheter that includes a tubular body **52** that may be provided with anchor supports **62** having a proximal section, a distal section, and a flex point **74**. See Frazier, Col. 9, ll. 50-66; Fig. 3A. Frazier does not teach the

claimed subject matter of the present invention. With respect to Claim 1, Frazier does not disclose a flexible catheter capable of assuming an angular configuration at a predetermined time during the surgical procedure, wherein the flexible catheter has an outer catheter and an inner catheter movably disposed in the outer catheter, the inner catheter adapted to bend within the outer catheter. Rather, the flex point **74** disclosed in Frazier may be forced radially outward only when the anchor support is outside the tubular body **52**. Id. Moreover, with respect to Claims 1, 8, 13, 18, and 19 Frazier does not disclose a sealant material associated with at least a portion of a fastener. The present Office Action states that the anchors (92) “can be considered sealant materials because they seal one organ to another.” Frazier, however, is completely silent with respect to providing a sealant material. There is nothing disclosed by Frazier that teaches or even suggests that the tissue anchors comprise sealant materials.

For at least the reasons set forth above, Applicants respectfully submit that Frazier fails to disclose, teach or suggest the invention claimed by Applicants. Reconsideration and withdrawal of the rejections are respectfully requested.

## **II. THE CLAIMS ARE PATENTABLE OVER U.S. PATENT No. 6,508,252 TO BERG ET AL.**

Claims 1, 3, and 19 were rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,508,252 to Berg, *et al.* (hereinafter “Berg”). Claims 4-8, 10-13, and 15-18 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Berg in view of U.S. Patent Publication No. 2004/0148267 to Sancoff, *et al.* (hereinafter “Sancoff”). These rejections are respectfully traversed.

Taken alone or in combination, neither Berg nor Sancoff teach Applicants’ claimed invention. Berg is directed to a medical grafting method and apparatus.

Sancoff is limited to an apparatus for placing multiple sutures in a vessel. The devices disclosed in Berg and Sancoff do not, however, disclose the apparatus and method claimed in the present application. With respect to Claim 1, neither Berg nor Sancoff discloses a flexible catheter capable of assuming an angular configuration at a predetermined time during the surgical procedure, wherein the flexible catheter has an outer catheter and an inner catheter movably disposed in the outer catheter, the inner catheter adapted to bend within the outer catheter. Moreover, with respect to Claims 1, 8, 13, 18, and 19, Berg does not disclose a sealant material associated with at least a portion of a fastener. The present Office Action concedes that "Berg only teaches using a fastener, but does not disclose the use of a glue, per se, that could be called a sealant material."

Further, there is no suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art to modify or combine Berg and/or Sancoff. First, the Examiner does not provide any authority in Berg to combine with the device disclosed in Sancoff, and vice versa. The Examiner merely states that "it would have been obvious to one having ordinary skill in the art at the time of the invention to apply glue to Berg's fastener." Second, the two references are directed to different medical fields. Berg is directed to methods and apparatus for installing tubing in a patient with a coronary bypass, while Sancoff is directed to methods for the surgical formation of anastomosis of vessels. The subject matter disclosed in the two references is so distinct that each is classified in a different primary class at the Patent Office.

For at least the reasons set forth above, Applicants respectfully submit that both Berg and Sancoff, taken alone or in combination, fail to disclose, teach or suggest the invention claimed by Applicants. Reconsideration and withdrawal of the rejections are respectfully requested.

**III. THE CLAIMS ARE PATENTABLE OVER U.S. PATENT No. 5,865,791 TO WHAYNE IN VIEW OF U.S. PATENT No. 5,209,741 TO SPAETH**

Claims 1, 3-8, 10-13, and 15-19 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,865,791 to Whayne, *et al.* (hereinafter “Whayne”) in view of U.S. Patent No. 5,209,741 to Spaeth (hereinafter “Spaeth”). This rejection is respectfully traversed.

Whayne is directed to systems and methods for reducing the regions of blood stasis and thrombus formation in atrial appendages in the human body. See Whayne, Col. 1, II. 5-10. A catheter **110** is disclosed having a hollow needle **66** that is reciprocally fitted in a distal tip member **114**. See Whayne, Col. 12, II. 10-31; Figs. 29-30. A pushing stylet **118** is reciprocally fitted within the hollow needle **66** and may be used to expel an expandable anchor **116**. *Id.* Spaeth is directed to a stiff tubular member for insertion into a patient wherein the cross-sectional size of the device may be optimized. See Spaeth, Abstract; Col. 1, II. 5-15.

Taken alone or in combination, neither Whayne nor Spaeth teach Applicants' claimed invention. Neither Whayne nor Spaeth discloses a flexible catheter capable of assuming an angular configuration at a predetermined time during the surgical procedure, wherein the flexible catheter has an outer catheter and an inner catheter movably disposed in the outer catheter, the inner catheter adapted to bend within the outer catheter. Indeed, the Interview Summary issued by the Patent Office states that

"Examiner agreed that U.S. Patent No. 5,865,791 does not read on the claims as presented in the After Final Amendment." Moreover, with respect to Claim 18, Whayne is silent as to securing a prosthetic graft to a vessel and does not disclose or suggest a method as presently claimed. With respect to Claim 19, Whayne does not disclose a delivery apparatus having a flexible catheter; and a penetration apparatus having a solid core disposed within the catheter, as presently claimed. The needle **66** disclosed in Whayne is hollow.

For at least the reasons set forth above, Applicants respectfully submit that both Whayne and Spaeth, taken alone or in combination, fail to disclose, teach or suggest the invention claimed by Applicants. Reconsideration and withdrawal of the rejections are respectfully requested.

#### **IV. CONCLUSION**

In view of the foregoing amendments and remarks, Applicants respectfully submit that the claims of the present invention define subject matter patentable over the references cited by the Office and that the application is in condition for allowance. Should the Office believe that anything further is desirable to place the application in better condition for allowance, the Office is invited to contact Applicants' undersigned attorney at the below listed telephone number.

The Commissioner is hereby authorized to charge any deficiency or credit any overpayment to deposit account number 03-2469. Moreover, if the deposit account contains insufficient funds, the Commissioner is hereby invited to contact Applicant's undersigned representative to arrange payment.

Respectfully submitted,

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